

REMARKS

In response to the Official Action dated December 31, 2001, Applicants have updated the continuation data of the present application at page 1 of the specification.

Applicant has further identified sequences with sequence ID numbers at page 7 of the application and for compounds numbered 39, 41, 42, and 43 at page 38 of the specification. Applicant now submits that they comply with the requirements of the sequence rules of 37 C.F.R. §§ 1.81-1.825 by providing herewith a copy of the sequence listing and C.F.R. containing each of the identified sequences.

Applicant has amended the specification at page 10 to correct a typographical error.

Applicant has amended the specification at page 58 to include an abstract.

Applicant has cancelled claim 1 of the application and has submitted new claim 40 in place of cancelled claim 1 in order to eliminate the use of brackets in cancelled claim 1. Further, Applicant has cancelled claims 2, 12-15, and 18-24, and has resubmitted those claims as new claims 41-52.

Regarding claim objections, Applicants have deleted the use of "t.Bu". Further, Applicants have responded to the objection to claim 21 by cancelling claim 21 and resubmitting claim 21 as new claim 49 and have eliminated the use of the term "being".

Claim Rejections - Obviousness Type Double Patenting

The Examiner has also rejected claims 1, 2, and 13-15 provisionally under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1, 2, and 3 of U.S. Patent No. 6,235,718. Additionally, the Examiner has rejected claims 12 and 18-24 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-3 of the '718 patent in view of Domen et al. (WO 91-03494), Spindel et al. (U.S. Patent No. 5,410,018) or Sakurada et al. (U.S. Patent No. 5,993,843). Applicant has submitted and attached hereto a Terminal Disclaimer so as to overcome this provisional obviousness-type double patenting rejection.

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected claims 1, 12-15, and 18-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. As discussed above, Applicant has cancelled claims 1, 12-15, and 18-24 and herewith submit new claims 40 and 42-52 which Applicant submits overcomes the rejections under 35 U.S.C. § 112, second paragraph.

In particular, the Examiner has rejected claim 1 for use of the phrase "e.g." as rendering the claim indefinite as it is unclear whether the limitations following the phrase are part of the claimed invention. In new claim 40, Applicant has eliminated all use of the phrase "e.g.".

The Examiner has rejected claim 1 as indefinite because of the use of the terms "Dap", "Pyr", and "Tip". The Examiner has stated that the terms Dap, Pyr, and Tip render the claim indefinite because these terms have not been explained in the specification. The Examiner has rejected claims 12-15 and 18-24 for being dependent on rejected claim 1 and for not correcting the deficiency of the claim from which they depend. In response, Applicant has amended the specification at page 9, lines 13-16 in order to include the full chemical names of "Dap", "Pyr", and "Tip" at their first occurrence in the specification. The Examiner has also rejected claim 1 as indefinite because of the use of the terms "Trp derivative", "etc.", and "amino acid derivatives". Claims 12-15 and 18-24 have also been rejected by the Examiner for being dependent on rejected claim 1. In response, Applicant has eliminated references to "etc." and to "amino acid derivatives". Further, Applicant submits that examples of Trp derivatives are given in the specification at least at page 9, line 15 and page 13, line 20.

The Examiner has rejected claim 2 as indefinite for containing non-elected peptides. In response, Applicants have cancelled claim 2 and herewith submit new claim 41 which only includes the peptide elected in response to the Examiner's restriction requirement.

The Examiner has rejected claim 18 as indefinite for the use of the terms "capable of" and "NPY" because the Examiner states that it is not clear to what extent the therapeutic composition controls an NPY mediated physiological response, and what the term "NPY" means. The Examiner has also rejected claim 18 as indefinite for containing non-elected inventions. The Examiner has further rejected claims 19-24 along with claim 18 for being dependent on rejected claim 18 and not correcting the

deficiency of the claim from which they depend. In response, Applicant has cancelled claims 18-24 and submitted new claims 46-52. New claim 46 has replaced the phrase "capable of controlling" and replaced with "capable of attenuating" to demonstrate that the therapeutic composition attenuates an NPY mediated physiological response. Applicant submits that this is demonstrated with reference to Figs. 1-3. New claim 46 also redefines the term "NPY" as human neuropeptide Y. Support for this amendment can be found at least at page 3, lines 11-12 of the specification. New claim 46 also depends solely from new claim 40, thus eliminating indefiniteness for containing non-elected inventions.

The Examiner has rejected claims 19-24 as indefinite because of the use of the term "to a subject in need of said compound". In response, in new claims 47-52, applicants have eliminated use of the phrase "to a subject in need of said compound".

Claim Rejections - 35 U.S.C. § 102

The Examiner has rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by Koenig et al. (EP 288965 November, 1988). The Examiner states that Koenig et al. teaches a peptide having a formula of L-B-A, where L is a lipophilic residue, B is a basic residue, and A is an aromatic residue. The Examiner also states that the peptide taught by Koenig also demonstrates a C terminal carboxyl group which is protected as an ester or amide as being useful as a phospholipid base A2 inhibitor. The Examiner points to compounds nos. 2, 3, 14, 40, 41 and 43 on pages 4-5 of Koenig as being included in claim 1 of the instant application. Applicant respectfully disagrees.

A review of the compound cited by the Examiner from Koenig demonstrates that a lysine (LYS) residue is included in each of the examples cited by the Examiner at the A2 position. With reference to cancelled claim 1, now new claim 40, of the present application, Applicant submits that the claim does not show a lysine as being a proper amino acid to be selected for the A2 position of the compound of the present invention. Thus, Applicant submits that Koenig does not show each and every claimed limitation of the present invention, and thus, claim 1, now new claim 40, is not anticipated under 35 U.S.C. § 102(b). Applicant therefore respectfully withdraws that the rejection be withdrawn.

Conclusion

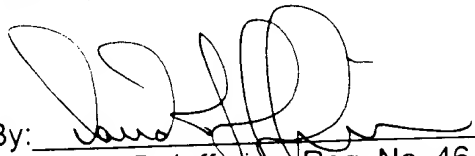
For the foregoing reasons, Applicant submits that all claims are patentable and a Notice of Allowance is respectfully requested.

Applicant believes that no fee is due. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to deposit account no. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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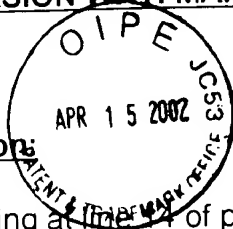
VERSION WITH MARKINGS TO SHOW CHANGES MADE

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In the specification:



Paragraph beginning at line 14 of page 1 has been amended as follows:

This application is a continuation-in-part of U.S. Application Serial No. 09/449,914, filed on December 2, 1999, now U.S. Patent No. 6,235,718, issued May 22, 2001, which is a divisional of U.S. Patent No. 6,013,633, issued January 11, 2000.

Paragraph beginning at line 1, page 14 has been amended as follows:

U.S. Pat. No. 5,328,899, Boublik *et al.*, issued Jul. 12, 1994, discloses NPY peptide analogs. Human Neuropeptide Y (NPY) has the formula: H-Tyr-Pro-Ser-Lys-Pro-Asp-Asn-Pro-Gly-Glu-Asp-Ala-Pro-Ala-Glu-Asp-Met-Ala-Arg-Tyr-Tyr-Ser-Ala-Leu-Arg-His-Tyr-Ile-Asn-Leu-Ile-Thr-Arg-Gln-Arg -Tyr-NH₂ (SEQ ID NO:1). Porcine and rat NPY have the same sequence except for Leu instead of Met in the 17-position. Porcine PYY is homologous having 11 different residues. NPY analogs and N-terminally-shortened fragments, e.g. NPY(18-36), which contain one or more specific D-isomer substitutions for the naturally occurring residues (as well as pharmaceutically acceptable salts thereof), dispersed in a pharmaceutically acceptable liquid or solid carrier, can be administered to mammals, including humans, to substantially lower blood pressure over an extended period of time or to counteract hypertension.

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Page 38, line 34 of the specification has been amended as follows:

39. ([[[Ac-Cys-Trp-Arg-Tyr-NH₂]]])₂ (SEQ ID NO: 2)

Page 38, line 36 of the specification has been amended as follows:

41. Dap-Ile-Trp-Arg-Glu-Arg-Tyr-NH₂ (SEQ ID NO: 3)

Page 38, line 37 of the specification has been amended as follows:

42. Leu-Ile-Trp-Arg-Glu-Arg-Tyr-NH₂ (SEQ ID NO: 4)

Page 38, line 38 of the specification has been amended as follows:

43. Cyclo([[[Trp-Arg-Nva-Arg-Tyr-]]]) (SEQ ID NO: 5)

Page 9, lines 13-16 have been amended as follows:

A1 is a D or L-amino acid selected from the group consisting of Cys, Leu, Dap (1,2-Diaminopropionic acid), Trp, Gln, a tethered amino acid with an indole ring (e.g., N-Me-Trp), Phe, Hyp, any Trp derivative (e.g., 2 chlorotryptophan, or Tcc); Ca Me-Trp, CaMe-Gln, Des-amino-Trp, Pyr (Pyroglutamic acid), Bth, Nal, Tcc, Asn, Nva, Abu, Tyr, Tic-OH, Phe, Tip (1,2,3,4-tetrahydronorharman-3-carboxylic acid), and Dip;

Page 10, lines 10-11 have been amended as follows:

Preferred compounds of formula (I) include those in which A1 is [Try] Trp or a pharmaceutically acceptable salt thereof.

Enclosed pages 46 and 47 have been inserted and previous page 46 has been renumbered to read 48.

Previous pages 47-57 have been renumbered to read pages 49-59.

In the claims:

Claims 1, 2, 12-15 and 18-24 have been cancelled.

Claims 40-52 have been added.

In the abstract:

The title on page 58 of the application has been amended as follows:

ABSTRACT

**COMPOUNDS FOR CONTROL OF APPETITE, BLOOD PRESSURE,
CARDIOVASCULAR RESPONSE, LIBIDO, AND CIRCADIAN RHYTHM**

**[Ambikaipakan Balasubramaniam
William T. Chance]**

[Background of the Invention]

In the drawings:

New Figures 1, 2, and 3 have been submitted.

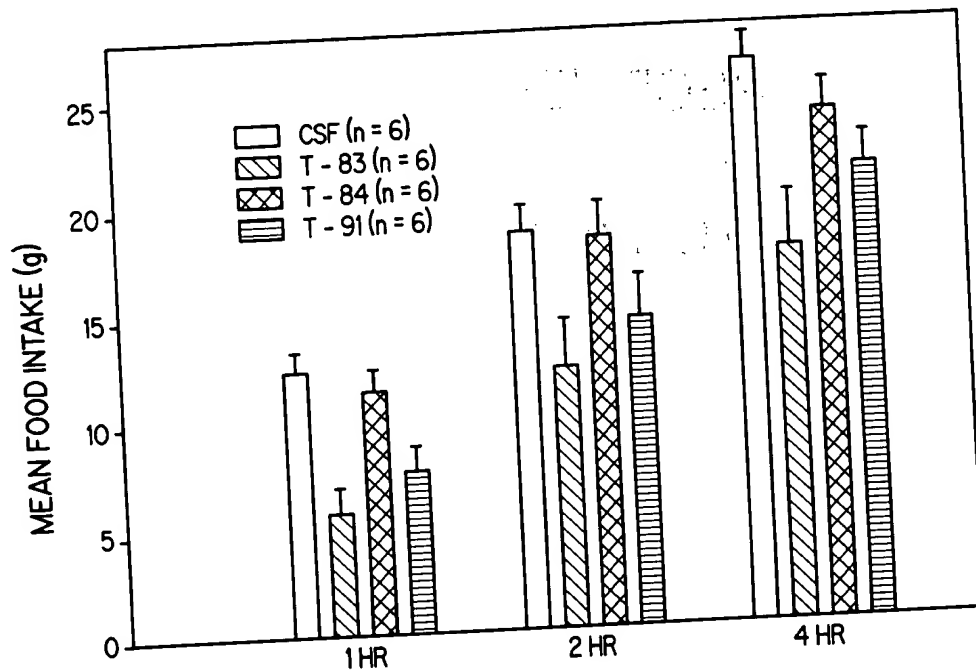


FIG. 1

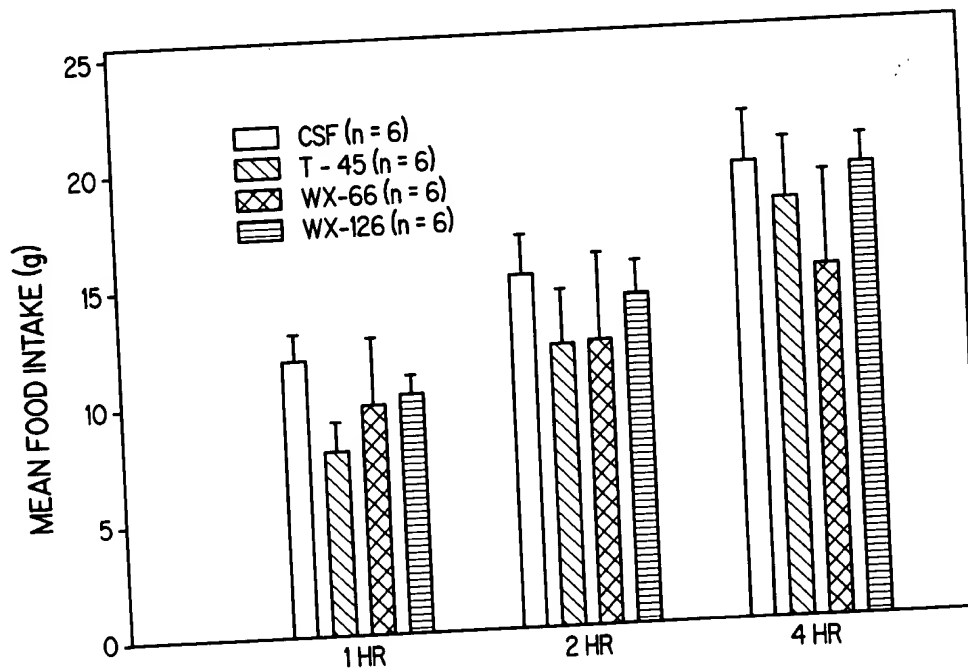


FIG. 2

APPROVED	O. G. FIG.	
BY	CLASS	SUBCLASS
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Author: Balasubramaniam et al.

App No.: UOC/136R

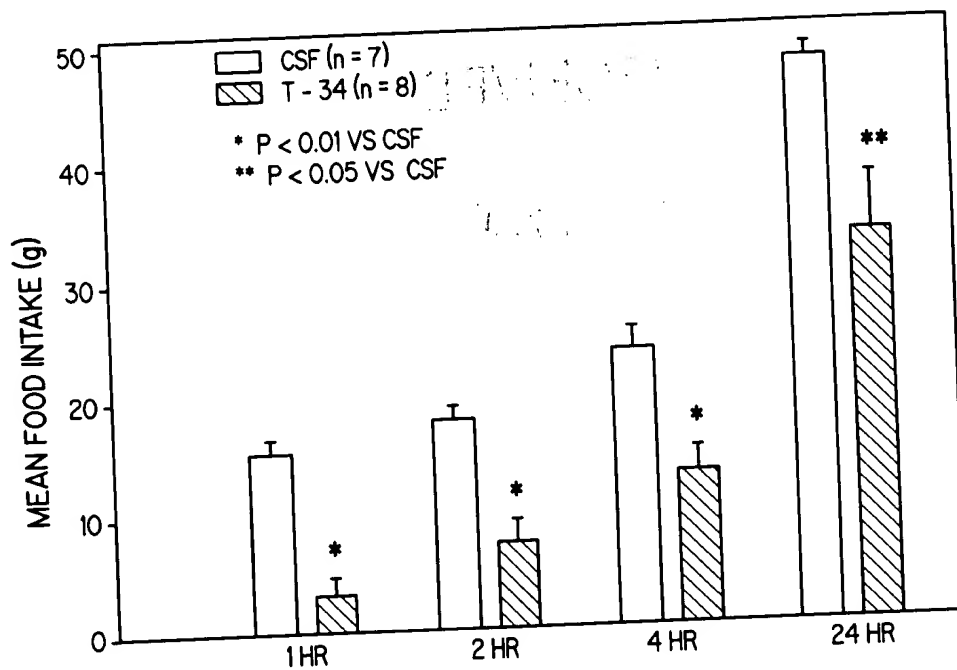
Title: Compounds for Control of Appetite, Blood Pressure,
Cardiovascular Response, Libido and Circadian Rhythm

FIG. 3